ANNEXURE

SRI RAMACHANDRA UNIVERSITY
(Declared under Section 3 of the UGC Act, 1956)

INSTITUTIONAL ETHICS COMMITTEE
(Other than Clinical Evaluation of Drugs / Procedures / Devices / Diagnostics / Herbal Remedies)

Chairperson:
Dr. A. Nalini

Member Secretary:
Dr. Pankaj B. Shah

Members:
Dr. Padmanabhi R.
Dr. Nirupa
Dr. Ramesh Harilal Iyer
Dr. C. D. Narayan
Dr. T. S. Lokeshwari
Dr. Leena Dennis Joseph
Dr. Pradyoth
Dr. L. V. K. S. Bhaskar
Dr. Vamshi Lavu
Mr. S. Rethina Kumar
Mrs. Sheeba Vinod

To
Dr. Pooja Adani
Full Time Ph.D. Research Scholar (ICMR Integrated Programme)
Dept. of Oral and Maxillofacial Pathology, SRU.

Dear Madam,

REF: IEC-NI/11/APR/22/19
SUB: Therapeutic Effects and Molecular Mechanisms of Antifibrosis Herbs on In-vitro fibroblast cell cultures in Oral submucous fibrosis.

Thank you for submitting the above proposal to the Institutional Ethics Committee, which was discussed in the meeting held on 15.4.2011. The Institutional Ethics Committee approves the project. Approval is given for in-vitro study only. You are advised to submit and procure separate permission for Human studies.

You are advised to be familiar with ICMR guidelines on Biomedical Research in human beings and also to adhere to the Principles of good clinical practice. You are required to submit the final report after the completion of study to the Institutional Ethics Committee.

Yours Sincerely,

(DR. PANKAJ B. SHAH)

Note: Please quote IEC Reference number in all future communications.
INFORMED CONSENT

I. Title of the project
   “In – vitro Human Buccal Fibroblast Cell Line Model for Screening Antifibrotic Activity of Plant Compounds in Oral Submucous Fibrosis”

II. Name of the Principle Investigator
   I Dr. Pooja Adtani, 1st year student of Integrated MDS-PhD Programme (No. PhD (Integrated)/-13-F.T./2010), Department Of Oral and Maxillofacial Pathology, Faculty of Dental Sciences, Sri Ramachandra University, I am doing my research work titled:
   “In – vitro Human Buccal Fibroblast Cell Line Model for Screening Antifibrotic Activity of Plant Compounds in Oral Submucous Fibrosis”
   The aim of my work is to find out an anti-fibrotic herb (drug) for patients affected with ‘Oral submucous fibrosis’ and help improve their condition.

III. Description of the Study:
   For my research work I would require a small tissue sample (4 mm in size) from your extracted tooth (3rd molar). Case sheet containing your clinical details together with the blood reports (if any) will be obtained by me on your consent. All information obtained from you will be kept confidential.
   • Voluntary participation
     Your participation will be completely VOLUNTARY. Number of participants will be decided in accordance to the sample size determined for the study.
   • Duration of participation with number of participants
     The duration of the participation will be only till the time of tooth extraction. The number of patients required for this study is 10.
   • Investigations to be performed (optional)
     Routine blood investigations will be performed, that will include (BT, CT, B.P, Random blood sugar).

   • Any alternative procedures or courses of treatment that might be as advantageous to the participant as the procedure or treatment to which s/he is being subjected.
     No alternative procedure or courses of treatment will be as advantageous to you as the procedure or treatment which is being given to you.
   • Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results.
     The tissue obtained will be subjected to immediate process of tissue culturing. The sample will not be stored as archives.
IV. **Possible risk to the participant**
The possible risks associated with the procedure include bleeding, postoperative pain and discomfort which can be encountered.

**Efforts taken to minimize the risks**

a. The tooth removal procedure will be performed after obtaining thorough medical history.
b. The patient will undergo routine hemogram and parameters of bleeding time, clotting time and INR before procedure.
c. Tooth removal procedure will be done under L.A with sterile instruments using aseptic techniques.
d. Bleeding will be controlled before sending the patient from the clinic.
e. Painkillers and antibiotics will be prescribed for the control of pain and infection.

**Postoperative instructions**

a. Ice pack should be kept on the operated site for 1-2 hrs after the procedure.
b. Avoid hot and spicy food for initial 3 days
c. No gargling
d. No smoking for atleast 1 week
e. No alcohol consumption for atleast 1 week
f. Consumption of cold items like ice-cream
g. Food should be soft in consistency
h. The medication prescribed should be taken on time.

V. **Possible Benefits to the participant**
My study would help finding out a drug (medicine) for the treatment of oral submucous fibrosis, this would be helpful for the community on whole.

VI. **Cost and Payments to the participant:**
There is no cost for participation in this study. Participation is completely VOLUNTARY and no payment will be provided.

VII. **Confidentiality**
Information obtained by you will be kept CONFIDENTIAL. Your name will not be used in reporting of information in publications or conference presentations.

VIII. **Participant’s right to withdraw from the study:**
You have the right to refuse to participate in this study, the right to withdraw from the study and the right to have your data destroyed at any point during or after the study, without penalty.

IX. **Voluntary consent by the participant**

PARTICIPATION IN THIS STUDY IS COMPLETELY VOLUNTARY, AND YOUR CONSENT IS REQUIRED BEFORE YOU CAN PARTICIPATE IN THIS STUDY.

I have read this consent form (or it has been read to me) and I fully understand the contents of this document and voluntarily consent to participate in the study. All of my questions concerning this study have been answered. If I have
any questions in the future about this study they will be answered by the investigators listed below. I understand that this consent ends at the conclusion of the study.

X. **Contact address with phone number:**

<table>
<thead>
<tr>
<th>PI - From (SRMC)</th>
<th>Collaborator (if any) outside SRMC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Pooja Adhani</td>
<td>None</td>
</tr>
<tr>
<td>IInd year MDS</td>
<td></td>
</tr>
<tr>
<td>Dept of Oral Pathology &amp; Microbiology</td>
<td></td>
</tr>
<tr>
<td>Faculty of Dental Sciences</td>
<td></td>
</tr>
<tr>
<td>Sri Ramachandra University</td>
<td></td>
</tr>
<tr>
<td>Chennai - 600116</td>
<td></td>
</tr>
</tbody>
</table>

By signing this form, I agree to participate in this study. A copy of this form has been given to me.

DATE:

NAME:

PARTICIPANTS SIGNATURE:

THUMB IMPRESSION:

WITNESS NAME:

WITNESS SIGNATURE:
CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this study to the above named individual, and I have discussed the potential benefits of this study participation. The questions the individual had about this study have been answered, and we will always be available to address future questions.

Date:                     Signature of person obtaining Consent
Name:                     
Signature of PI

In-vitro human buccal fibroblast cell line model for screening antifibrotic activity of plant compounds in Oral Submucous Fibrosis
In-vitro human buccal fibroblast cell line model for screening antifibrotic activity of plant compounds in Oral Submucous Fibrosis
Annexure

**Institute of Herbal Science**

**Plant Anatomy Research Centre**

Prof. P. Jayaraman, Ph.D.
Director
Retd., Professor, Presidency College Chennai-5

**Authentication Certificate**

Based upon the organoleptic / macroscopic / microscopic examination of fresh / market sample, it is certified that the specimen given by Dr. Poja Aditani, Research Fellow, Dept. of Oral Pathology & Micro, is identified as follows:

**Sri Ramakrishna University, Chennai, Biology.**

**Binomial:** Ocimum basilicum L.

**Family:** Lamiaceae (Subfamily: Labiatae)

**Synonym(s):** Nil

**Regional names:** Eng. Basil; Tamil, Karumthulli

**Reg. No. of the certificate:** PARE/2013/2124

**References:**

**Date:** 01.03.2013

(Prof. P. Jayaraman)

Prof. P. Jayaraman, Ph.D.
Director,
Institute of Herbal Botany
Plant Anatomy Research Centre,
No. 4. II Street, Sakshi Nagar,
West Tambram, Chennai-45.
Phone: 44-22262326, Cell: 9939136959
E-mail: herbalparc@yahoo.com

In-vitro human buccal fibroblast cell line model for screening antifibrotic activity of plant compounds in Oral Submucous Fibrosis
Annexure

In-vitro human buccal fibroblast cell line model for screening antifibrotic activity of plant compounds in Oral Submucous Fibrosis